K092229

# Special 510(k): Device Modification
# Thyretain ™ TSI Reporter BioAssay

DIAGNOSTIC HYBRIDS
*Integrating Science and Humanity*

## DATE OF PREPARATION OF 510(k) SUMMARY

July 15, 2009

## APPLICANT

DIAGNOSTIC HYBRIDS, INC.
1055 East State Street
Suite 100
Athens, OHIO 45701

MAY 18 2010

## CONTACT INFORMATION

Ronald H. Lollar
Senior Director, Product Realization, Management, and Marketing
E-mail: lollar@dhiusa.com
Telephone: 740-589-3300
Desk Extension: 740-589-3373
FAX: 740-593-8437

## DEVICE NAME

Trade name: Thyretain ™ TSI Reporter BioAssay
Common name: TSI Reporter
Classification name: System, Test, Thyroid Autoantibody
Product Code: JZO
Regulation: 21 CFR § 866.5870, Thyroid Autoantibody Immunological Test

## LEGALLY MARKETED DEVICE

Thyretain ™ TSI Reporter BioAssay (TSI Reporter), K083391

## DESCRIPTION of DEVICE MODIFICATION

The number of wells tested per Positive, Reference and Negative control has been reduced from three to two for each. The number of wells tested per patient specimen has been reduced from three to two.

## INTENDED USE

The Thyretain ™ TSI Reporter BioAssay is intended for the qualitative detection in serum of thyroid stimulating autoantibodies to the thyroid stimulating hormone (TSH) receptors (TSHRs) on the thyroid. The detection of these stimulating autoantibodies, in conjunction with other clinical and laboratory findings, may be useful as an aid in the differential diagnosis of patients with Graves' disease (GD).

## ASSESSMENT OF NON-CLINICAL PERFORMANCE DATA FOR EQUIVALENCE

Not Applicable

## ASSESSMENT OF NON-CLINICAL PERFORMANCE DATA FOR EQUIVALENCE

The risk analysis method used to assess the impact of the modification was a Failure Modes and Effects Analysis (FMEA). Based on the analysis of the study site data (see Attachment 2) the modification poses little risk.

## BIOCOMPATABILITY

Not applicable

## STERILIZATION

Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Diagnostic Hybrids, Inc
c/o Mr. Ronald H. Lollar
Senior Director, Product Realization, Management and Marketing
1055 East State Street, Suite 100
Athens, Ohio 45701

MAY 18 2010

Re: k092229

| | |
|---|---|
| Trade/Device Name: | Thyretain ™ TSI Reporter BioAssay |
| Regulation Number: | 21 CFR §866.5870 |
| Regulation Name: | Thyroid autoantibody immunological test system |
| Regulatory Class: | Class II |
| Product Code: | JZO |
| Dated: | May 14, 2010 |
| Received: | May 17, 2010 |

Dear Mr. Lollar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indication for Use

510(k) Number (if known): k092229

Device Name: Thyretain ™ TSI Reporter BioAssay

Indication For Use:

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Prescription Use ✓ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k092229